

the vaccine, once obtained, is not then serially administered and passaged through tissue culture to reduce its pathogenicity prior to its ultimate administration to individual poultry members. Support for this amendment may be found in the specification with reference to Example 1 bridging pages 5 and 6. It is here that this feature of the invention is implicitly set forth. Moreover, a careful reading of the *entire* specification makes clear that this has been the applicants' invention all along.

In addition, claims 15 and 19 have been amended to assume the salient portions of now-cancelled claims 17 and 20, respectively. Claim 18 has been amended to recite proper dependency from claim 16. Claims 21 and 22 have each been amended to recite proper dependency from claim 19.

New claims 23 and 24 are directed to further embodiments of the invention. Support therefor may be found, *inter alia*, in the specification at page 1, starting at line 22, as well as the paragraph which brackets pages 2 and 3. Submission of these claims does not diminish applicants' belief in the patentability of the remaining claims.

Entry of the foregoing amendments and new claims is respectfully requested.

Attached hereto is a marked-up version of the changes made to the claims by the amendments set forth above. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Claims 1, 13, 15, and 19 were objected to under 35 U.S.C. §132 for alleged-new-matter. Applicants respectfully request the Office to reconsider and withdraw this objection for the reasons set forth below.

It is respectfully submitted that the situation in the present application is not similar to that set forth in Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 56 USPQ2d 1481, 1487. In that case, it was apparent that the patentees had selected an obscure embodiment buried in two of their formulations. They then tried to expand that embodiment to encompass the entire invention. In other words, their

invention was really an afterthought - and an attempt to take a small piece of the original disclosure and make it into the central focus of the claims. In the present application, however, it is clear from the start what the applicants' invention was, and the presently amended claims simply make that concept explicit. Applicants' intent was always to take a commercial vaccine and then administer it directly to fertile poultry eggs, *without further attenuation via serial passaging*. And this fact is unmistakably apparent once the specification is read in its entirety. Applicants have not described or alluded to anything else in their specification. Put another way, the skilled artisan, upon reading applicants' original disclosure, would "immediately discern the limitation at issue." Id. At 1483, citing Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). In addition, the amendment is fully consistent with the CAFC's further holding in Purdue that "the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue." Id. At 1483. On this basis, applicants therefore respectfully urge the PTO to withdraw the new matter objection.

Claims 1, 7 – 13, 15, 16, 18 and 19 stand rejected under 35 U.S.C. §102(b) as being anticipated by Wakenell et al.'s article in the American Journal of Vet. Research entitled "*Chicken embryonal vaccination with avian infectious bronchitis virus*". This rejection is again respectfully traversed due to the fact that the authors do not describe a vaccine having the dosage ranges set forth by the present applicants. In addition, the authors do not describe a method of administering a vaccine directly to poultry eggs without further serial passaging thereof. For at least these reasons, the Wakenell et al. article cannot be held to anticipate the presently claimed invention. Withdrawal of the rejection is therefore respectfully requested.

Claims 2 – 6, 14, 17, 20 – 22 were rejected under 35 U.S.C. §103(a) as being obvious over the cited Wakenell et al. article cited above. This rejection is also respectfully traversed.

Wakenell et al. do not describe a vaccine which, once obtained, is not then serially passaged. Instead, the reference actually seems to *mandate* subsequent serial passaging in order to effectively reduce pathogenicity. As their

article further details, Wakenell et al. were stymied to find a suitable live vaccine against IBV for chickens. In fact, the authors expressly teach away from the present invention by declaring:

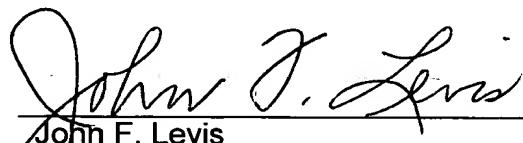
"V-IBV was found to be highly pathogenic for embryos, as measured by both hatchability and survival. . . Dilution of V-IBV from 10⁵ EID₅₀ to 10² EID₅₀ did not significantly (P > 0.05) improve either hatchability (48%) or survival (0%)."

In other words, the authors predicted scant success in fashioning a vaccine as set forth by the present applicants. As quoted above, they felt that any further reduction in the dosing would have been just as lethal, and therefore would not have produced effective results. This would have no doubt dissuaded the skilled artisan from proceeding in the manner as claimed. There is simply no teaching or hint in the reference that an IBV vaccine or method of vaccination, having the claimed characteristics, could be developed. In fact, the present applicants defied the conventional thinking by producing a vaccine in the manner they have recited. They proceed in a direction contrary to that which was commonly accepted by the state of the art. They are therefore entitled to patent protection for their discovery.

Based on the foregoing, it is respectfully submitted that the claimed invention is not obvious in view of Wakenell et al., and withdrawal of the obviousness rejection is therefore respectfully urged.

The application is believed to be in proper condition for allowance, and prompt, favorable action thereon is earnestly solicited. Should Examiner Foley feel that any other point requires consideration, then she is cordially invited to contact the undersigned.

Respectfully submitted,


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VERSION WITH MARKINGS TO SHOW CHANGES MADE

AMENDED CLAIMS:

1. (Twice Amended) A process for protecting a host poultry animal, comprising a) obtaining a vaccine against infectious bronchitis; and b) thereafter administering [a] said vaccine, without serially passaging said vaccine through tissue culture, in ovo to a fertile egg containing an embryo of the host animal; [and] wherein [the] said vaccine comprises an immunogenically-effective amount of a live, avirulent strain of infectious bronchitis virus[, and further wherein the vaccine is not serially passaged through tissue culture].
13. (Twice Amended) A process for protecting chickens from exposure to virulent strains of IBV, [comprising] consisting essentially of obtaining a commercial vaccine against IBV and then administering in ovo to fertile chicken eggs [a] said vaccine, [that is not serially passaged and] wherein said vaccine comprises, on a per egg basis, an immunogenically-effective amount of a live, avirulent strain of infectious bronchitis virus.
15. (Twice Amended) [A] An in ovo vaccine for protecting chickens from exposure to virulent infectious bronchitis virus, wherein said vaccine [is not serially passaged through tissue culture, comprising:] comprises a solution containing, on a chicken egg basis, a live avirulent strain of infectious bronchitis virus in an immunogenically-effective amount within the range of about 10^{-1.0} EID₅₀ per egg to about 10^{2.0} EID₅₀ per egg.
18. (Amended) The vaccine of claim [17] 16, wherein the vaccine contains substantially no virus neutralizing factor.
19. (Amended) A [non-serially passaged] poultry vaccine against infectious bronchitis virus (IBV) comprising a live avirulent strain of infectious bronchitis virus in an immunogenically effective amount for in ovo administration of about 10^{-1.0} EID₅₀ per dose to about 10^{2.0} EID₅₀ per dose.
21. (Amended) The vaccine of claim [20] 19, wherein said vaccine comprises about 10^{0.0} EID₅₀ per dose to about 10^{2.0} EID₅₀ per dose.

22. (Amended) The vaccine of claim [20] 19, wherein said vaccine comprises about $10^{0.0}$ EID₅₀ per dose to about $10^{1.0}$ EID₅₀ per dose.

NEW CLAIMS:

23. (New) The process of claim 1, wherein said vaccine is commercially available.

24. (New) A method of vaccinating a poultry animal against infectious bronchitis (IB), which comprises obtaining a commercial vaccine against IB and thereafter directly administering said vaccine in ovo to a member selected from the group consisting of chickens, turkeys, ducks, geese, bantams, quail and pigeons, wherein said vaccine contains a live, nonvirulent strain of IB in a quantity sufficient to confer immunity.